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14498/PTO Rev. 10/95		U.S. Department of Commerce Patent and Trademark Office		Complete if Known	
				Application Number	10/17716, 030 10/1671, 135
				Filing Date	
				First Named Inventor	Tito Mattinen
				Group Art Unit	
				Examiner Name	
Sheet	2	of	15	Attorney Docket Number	119075-00058

## OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.*	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, country, where published, source.	T <sup>2</sup>
JP		European Journal of Clinical Investigation, Vol. 10, pp. 27-33, (1980). T. Mattinen "Phytosterolemia, Anthropotropia and Premature Atherosclerotic Arterial Disease: A Case with High Plant Sterol Absorption, Impaired Sterol Elimination and Low Cholesterin Synthesis"	
		Scand. J. Gastroenterol, Vol. 23, pp. 967-972, (1988). K. Nikodin, et al. "Serum Cholesterol Precursors, Cholestanol, and Plant Sterols in Primary Biliary Cirrhosis"	
		Z. Klin. Chem. Biochem., Vol. 9, pp. 47-52, (1971). T. Mattinen, et al. "Sole Salts, Sterols, Sterol Esters, Glycendes and Fatty Acids in Neutral and OI Phases of Intestinal Contents During Fat Digestion in Man"	
		Journal of Lipid Research, Vol. 20, pp. 648-653, (1979). A. Hassan, et al. "Intestinal Absorption and Lymphatic Transport of Cholesterol and $\beta$ -Sisosterol in the Rat"	
		Journal of Organic Chemistry, Vol. 25, pp. 1203-1219, (1960). A. Kuusia, et al. "Preparation and Certain Physical Properties of Some Plant Steryl Esters"	
		Synthetic Communications, Vol. 16, pp. 1423-1430, (1985). M. Serpa, et al. "A Convenient Method of Esterification of Fatty Acids, Preparation of Alkyl Esters, Sterol Esters, Wax Esters and Triacylglycerols"	
		Lipids, Vol. 12, pp. 242-244, (1977). A. Prabhudesai "A Simple Method for the Preparation of Cholesterol Esters"	
		Chemistry and Physics of Lipids, Vol. 15, pp. 216-221, (1975). S. Lenz, et al. "A Simple Method for the Synthesis of Cholesterol Esters in High Yield"	
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Examiner Signature	<i>Car</i>	Date Considered	<i>7/8/8</i>
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74405/PTO Rev. 10/93	U.S. Department of Commerce Patent and Trademark Office	
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Sheet	13	d - 15

Complete if Known

Application Number	div-10-097719-030 10/4787135
Filing Date	
First Named Inventor	Titu Meithren
Group Art Unit	
Examiner Name	
Attorney Docket Number	019075-00058

## OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.*	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, country, where published, source.	T
✓		Circulation, Vol. 7, pp. 702-708, (May 1953), O. Potatz "Reduction of Blood Cholesterol in Man"	
		Act. Soc. Esp. Biol. Med., Vol. 78, pp. 143-147, (1951), O. Petersen "Effect of Soybean Sterols in the Diet on Plasma and Liver Cholesterol in Chick"	
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		Journal of Lipid Research, Vol. 10, pp. 304-315, (1969), S. Grundy, et al. "The Interaction of Cholesterol Absorption and Cholesterol Synthesis in Man"	
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## LIST OF PRIOR ART CITED BY APPLICANT

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Application Number	10,678,138
Filing Date	10/10/85
First Named Inventor	Tatsu Mizutani
Group Art Unit	
Examiner Name	
Attorney Docket Number	019075-00058

### OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, country, where published, source.	T
Lp		Chemical Abstracts, Vol. 115, No. 1, (1991), T. Heinemann, et al. "Mechanisms of Action of Plant Sterols on Inhibition of Cholesterol Absorption: Comparison of Stigmasterol and Sisosterol"	
		Chemical Abstracts, Vol. 112, No. 7, (1990), I. Izada, et al. "Effects of Sisosterol and Sisostanol and Nicotin Salinity of Cholesterin"	
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		Chemical Abstracts, Vol. 88, No. 3, (1978), M. Sugano, et al. "A Comparison of Hypocholesterolemic Activity of $\beta$ -Sisosterol and $\beta$ -Sisostanol in Rats"	
		Chemical Abstracts, Vol. 71, No. 1, (1969), T. Tsuchiya "Sisosterol Fatty Acid Ester"	
		International Search Report, dated 12/11/91.	
		International Preliminary Exam Report, dated 08/04/93.	
		Copy of Written Opinion from International Preliminary Exam Authority, dated 04/14/93.	

Examiner Signature	Cler	Date Considered	3/08
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Sheet

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Complete if known

Application Number	DE 10 09 712 030 0127730
Filing Date	
First Named Inventor	Tatsu Matsuura
Group Art Unit	
Examiner Name	
Attorney Docket Number	019075-00058

### OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initiator*	Cite No.*	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, country, where published, source.	T
O		Lipoprotein Metabolism, pp. 112-118, (1976), (Ed. H. Gretz, Berlin, Heidelberg, New York: Springer-Verlag). S. Grundy, et al. "Effects of Low Dose Phytosterols on Cholesterol Absorption in Man"	
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		Atherosclerosis, Vol. 30, pp. 227-237, (1978). I. Ikeda, et al. "Comparison of Absorption and metabolism of $\beta$ -Sisosterol and $\beta$ -Sisostanol in Rats"	
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## LIST OF PRIOR ART CITED BY APPLICANT

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Sheet

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of

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		Complete if Known	
Application Number		D19075-00058 09-6719,090 10/678,135	
Filing Date			
First Named Inventor		Taru Mattila	
Group Art Unit			
Examiner Name			
Attorney Docket Number		D19075-00058	

### OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.*	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, country, where published, source.	T
O		Journal of Lipid Research, Vol. 18, pp. 203-210, (1977), R. Jandacek, et al. "Effect of an Aqueous Phase on the Solubility of Cholesterol in an Oil Phase"	
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Examiner Signature	Cea	Date Considered	7/08
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## LIST OF PRIOR ART CITED BY APPLICANT

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Sheet

7

of 15

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Application Number	2007-09-713,030
Filing Date	10/16/98
First Named Inventor	Isaac Meitzen
Group Art Unit	
Examiner Name	
Attorney Docket Number	019075-00058

### OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initiator*	Case No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, country, where published, source.	T
<i>✓</i>		European Journal of Clinical Pharmacology, Vol. 40 (Suppl.1), pp. 539-553, (1991), T. Heinemann, et al. "Mechanisms of Action of Plant Sterols on Inhibition of Cholesterol Absorption"	
		The American Journal of Clinical Nutrition, Vol. 35, pp. 697-702, (1982), F. Mattson, et al. "Optimizing the Effect of Plant Sterols on Cholesterol Absorption in Man"	
		J. Clin. Invest., Vol. 80, pp. 578-581, (August 1987), Y. Kesaniemi, et al. "Intestinal Cholesterol Absorption Efficiency in Man is Related to Apoprotein E Phenotype"	
		Annals of Clinical Research, Vol. 20, pp. 26-31, (1988), Y. Kesaniemi, et al. "Metabolic Epidemiology of Plasma Cholesterol"	
		Journal of Lipid Research, Vol. 27, pp. 227-235, (1986), C. Ehnholm, et al. "Apolipoprotein E Polymorphism in the Finnish Population: Gene Frequencies and Relation to Lipoprotein Concentrations"	
		The Lancet, Vol. 2, pp. 1281, (November 1988), T. Meitzen, et al. "Serum Cholesterol Response to Dietary Cholesterol and Apoprotein E Phenotype"	
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		The (Journal of Clinical Investigation, Vol. 49, pp. 952-957, (1970), G. Salen, et al. "Metabolism of $\beta$ -Sitosterol in Man"	
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<i>✓</i>		Journal of Lipid Research, Vol. 30, pp. 1319-1330, (1989), G. Salen, et al. "Increased Sterol Absorption, Decreased Removal, and Expanded Body Pools Compensate for Reduced Cholesterol Synthesis in Sitosterolemia with Xanthomatosis"	

Examiner Signature	<i>Cera</i>	Date Considered	3/88
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## LIST OF PRIOR ART CITED BY APPLICANT

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Sheet	8	of	15	Attorney Docket Number	219975-00058
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### OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Case No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue numbers, publisher, country, where published, source.	T
29		<i>Journal of American Oil Chemists' Society</i> , Vol. 54, pp. 47-50, (1977), D. Chabanov, et al. "Alterations in Glyceride Composition During Interesterification of Mixtures of Sunflower Oil with Lard and Tallow"	
		<i>"Thermodynamic and Molecular Determinants of Sterol Solubilities in Egg Yolk Mixture"</i> , Vol. 28, pp. 1144-1155, (1987), M. Armstrong, et al.	
		<i>Pediatric Pharmacology and Therapeutics</i> , Vol. 122, No. 2, pp. 232-236, (1993), M. Becker, M.D., et al. "Treatment of Severe Familial Hypercholesterolemia in Childhood with Sitostanol and Sitostanol"	
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		<i>Steroids</i> , Vol. 40, No. 2, pp. 233-243, (1982), S. Dayal, et al. "Identification of 5 $\alpha$ -Sterols in Patients with Sitostostenosis and Xanthomatosis: Stereochemistry of the Protonolysis of Steroidal Organoboranes"	
		<i>J. Sci. Food Agric.</i> , Vol. 71, pp. 383-391, (1996), P. Dutta, et al. "Saturated Sterols (Sitanols) in Unhydrogenated and Hydrogenated Edible Vegetable Oils and in Cereal Lipids"	
		<i>Treatment of Severe Dyslipoproteinemia in the Prevention of Coronary Heart Disease</i> , Vol. 4, pp. 57-59, (1993) H. Gyling, et al. "Serum Cholesterol Lowering by Dietary Sitostanol is Associated with Reduced Absorption and Synthesis of Cholesterol and Decreased Transport of LDL Apoprotein B in Men with Type II Diabetes"	
		<i>Diabetologia</i> , Vol. 37, pp. 773-780, (1994), H. Gyling et al. "Serum Cholesterol and Cholesterol and Lipoprotein Metabolism in Hypercholesterolemic NIDDM Patients Before and During Sitostanol Ester-Mannane Treatment"	
		<i>Journal of Lipid Research</i> , Vol. 36, pp. 1807-1812, (1995), H. Gyling et al. "Sitostanol Ester Margarine in Dietary Treatment of Children with Familial Hypercholesterolemia"	
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		<i>J. Nutr. Sci. Vitaminol.</i> , Vol. 27, pp. 243-252, (1981), I. Ikeda et al. "Antihypercholesterolemic Activity of $\beta$ -Sisosterol in Rabbits"	

Examiner Signature	<i>Cern</i>	Date Considered	<i>7/08</i>
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SERIAL N 10/678,355  
Date of 9/13/930

## LIST OF REFERENCES CITED BY APPLICANT

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MIETTENEN et al.

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## OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

28	AM	POLLAK, O.J., "Effect of Plant Sterols on Serum Lipids and Atherosclerosis", Pharmac. Ther. Vol. 31, pp. 177 to 208, 1985.
	AN	JIMÉNEZ DE BLAS, et al., "Determination of Sterols by Capillary Column Gas Chromatography. Differentiation Among Different Types of Olive Oil: Virgin, Refined, and Solvent-Extracted" JAOCS, Vol. 73, no. 12, pp. 1685-1689 (1996).
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LIST OF REFERENCES CITED BY APPLICANT <i>(Use several sheets if necessary)</i>		APPLICANT MIETTINEN, et al.	
		FILING DATE Herewith	GROUP unknown

## OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

↑	BA	KOBAYASHI et al., Translation of JP 57-206336 (1982).
	BB	PETERSON et al., "Depression of plasma cholesterol in human subjects consuming butter containing soy sterols", Fed. Proc., 1956, Vol. 15, Page 569.
	BC	VANHANEN et al., "Effects of unsaturated and saturated dietary plant sterols on their serum contents", Clinica Chimica Acta, Vol. 205, 1992, Pages 97-107.
	BD	VANHANEN et al., "Serum cholesterol, cholesterol precursors, and plant sterols in hypercholesterolemic subjects with different apoE phenotypes during dietary sitostanol ester treatment", Journal of Lipid Research, Vol. 34, 1993, Pages 1535-1544.
	BE	Preliminary Opinion prepared by the Opposition Division in European Patent No. 0 594,612 (granted on Application No. 91908435.0), December 17, 1999, pages 1-7.
	BF	Main Request - May 4, 1999 filed in the European Patent Office in European Patent No. 0 594 612 (granted on Application No. 91908435.0)
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→	BK	Opposed patent as filed in Finnish; Title: A substance for lowering high cholesterol level in serum and a method for preparing the same; Inventors: MIETTINEN et al.
→	BL	Norm NEN 3428
	BM	

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LIST OF REFERENCES CITED BY APPLICANT <i>(Use several sheets if necessary)</i>		APPLICANT MIETTINEN, et al.	
		FILING DATE Herewith	GROUP unknown

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	AB	4,160,850	07/1979	HALLSTROM et al.			
	AC	1,413,102	11/1975	JANDACEK			
X	AD	3,852,311	12/1974	NICHOLAS et al.			

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Op	AE	WO 98/06405	02/1998	PCT			
	AF	WO 96/38047	12/1996	PCT			
	AG	567,202	12/1958	CANADA			
	AH	WO 92/19640	11/1992	PCT			
	AI	967616	09/1996	ZA			
X	AJ	WO 97/42630	11/1997	PCT			
	AK						

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Op	AL	Opposition in corresponding Australian Patent Application Serial No. 736020.
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FORM PTO-1449	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO. 019075-00058	SERIAL NO. 10/028,135 D-097743,030
LIST OF REFERENCES CITED BY APPLICANT  (Use several sheets if necessary)		APPLICANT MIETTINEN et al.	
		FILING DATE Herewith	GROUP unknown

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dy	AG	EP 0 898 896 A1	03/1999	EPO			
dy	AH	0 203 277 A2	12/1986	EPO			

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9	AM	Appeal against Decision of Opposition Division filed in the EPO on February 21, 2002 including Main Request, Opponent's schematic representation of sitosterol and sitostanol and Proprietor's schematic representation of sitostanol, sitosterol and cholesterol.
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LIST OF REFERENCES CITED BY APPLICANT  (Use several sheets if necessary)				APPLICANT MIETTINEN et al.	
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3	AD EP 0 911 385 A1		EP			
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3	AF	Page 2 of the Written Opinion of WO 92/19640
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FORM PTO-1449	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO. 019075-00058	SERIAL NO. 101678,135 Date of 08/04/2002,100-
LIST OF REFERENCES CITED BY APPLICANT  (Use several sheets if necessary)		APPLICANT MIETTINEN et al.	
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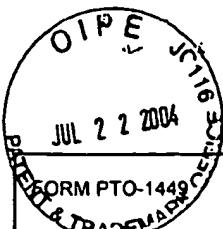
FORM PTO-1449	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO. D19075-00058	SERIAL NO. 101678,135 DIA 08743,030
LIST OF REFERENCES CITED BY APPLICANT  (Use several sheets if necessary)		APPLICANT Miettinen et al.	
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DT	AA	Opposition by Unilever N.V. (OPPO 01), European Patent Application No. 91 908 435.0 435.0-2117/594612, September 6, 2002.
	AB	RUDD et al., "Pancreatic carboxyl ester lipase (cholesterol esterase)", in Lipases, 1984, pages 185-204 (Ed. Rörgström)
	AC	Brockhoff et al, "Cholesterol Esterase", in Lipolytic Enzymes, pages 176-193.
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N	AI	Department of Health and Human Services, "Food Labeling: Health Claims; Plant Sterol/Stanol Esters and Coronary Heart Disease; Interim Final Rule", Federal Register, Vol. 65, No. 175, September 2000.

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FILING DATE		GROUP	
October 6, 2003		1614	

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